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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
10/609,004	06/27/2003	Ming H. Wu	MEM-0005	8425
23413 7:	590 06/17/2005		EXAMINER	
CANTOR COLBURN, LLP			MORILLO, JANELL COMBS	
55 GRIFFIN R BLOOMFIELI			ART UNIT PAPER NUMBER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

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		Application No.	Applicant(s)	v				
Office Action Summary		10/609,004	WU, MING H.					
		Examiner	Art Unit					
		Janelle Combs-Morillo	1742					
Period 1	The MAILING DATE of this communication app for Reply	ears on the cover sheet with the	correspondence address					
THE - Ext - If th - If N - Fail	MAILING DATE OF THIS COMMUNICATION. ensions of time may be available under the provisions of 37 CFR 1.13 or SIX (6) MONTHS from the mailing date of this communication. ee period for reply specified above is less than thirty (30) days, a reply operiod for reply is specified above, the maximum statutory period was the provision of the provision o	36(a). In no event, however, may a reply be to within the statutory minimum of thirty (30) do will apply and will expire SIX (6) MONTHS from the application to become ABANDON.	imely filed  ays will be considered timely.  m the mailing date of this communication.  IED (35 U.S.C. § 133).					
Status								
1)⊠	Responsive to communication(s) filed on 27 Ju	ıne 2003.						
·		action is non-final.						
3)								
	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.							
Disposi	tion of Claims							
4)⊠	Claim(s) <u>1-53</u> is/are pending in the application.							
	4a) Of the above claim(s) is/are withdrawn from consideration.							
5)□	Claim(s) is/are allowed.							
6)⊠	Claim(s) <u>1-53</u> is/are rejected.							
7)[	Claim(s) is/are objected to.							
8)□	Claim(s) are subject to restriction and/or election requirement.							
Applicat	tion Papers							
9)	The specification is objected to by the Examine	r.						
10)	10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.							
	Applicant may not request that any objection to the	= , ,	• •					
	Replacement drawing sheet(s) including the correcti	• • • • • • • • • • • • • • • • • • • •	•					
11)	The oath or declaration is objected to by the Ex	aminer. Note the attached Offic	e Action or form PTO-152.					
Priority	under 35 U.S.C. § 119							
•	Acknowledgment is made of a claim for foreign All b) Some * c) None of:  1. Certified copies of the priority documents 2. Certified copies of the priority documents 3. Copies of the certified copies of the priority application from the International Bureau	s have been received. s have been received in Applica ity documents have been receiv	tion No					
* ;	See the attached detailed Office action for a list of	, , , ,	red.					
Attachmer			(DTO (10)					
	ce of References Cited (PTO-892) ce of Draftsperson's Patent Drawing Review (PTO-948)	4) 🔲 Interview Summar Paper No(s)/Mail [						
3) 🛛 Infor	rmation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) er No(s)/Mail Date <u>51204_122903_11190</u> <b>3</b>		Patent Application (PTO-152)					

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#### **DETAILED ACTION**

## Claim Objections

1. Claims 40-44 are objected to because of the following informalities: claims 40-44 are process type claims, dependent on independent product by process claim 39. Because of said dependency, claims 40-44 are interpretted by the examiner to also be product by process type claims. Said claims need to be amended to be consistant with typical product by process preamble claim language. Appropriate correction is required.

## Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 3. Claims 1-15, 22, 24, 39, 41, 43-51 are rejected under 35 U.S.C. 102(b) as being anticipated by Schetky et al (US 6,258,182).

Schetky teaches a beta phase titanium alloy preferably comprising: 10-12% Mo, 2.8-4% Al, 0-2% Cr, and 0-4% Nb (see abstract), which overlaps or touches the boundary of the composition in instant claim 1 and 45. Schetky teaches examples within the instant composition range (see Table III, alloys 27, 28, and 36).

Concerning the process limitations of dependent claims 2, 39, 41, 43-45, Schetky teaches cold working a wire up to 20% reduction, further heat treatment including solution heat treating 780-880°C (column 12 line 60), and aging at 200-400°C (column 11 lines 18) for 0.1-10,000 min

(see Fig. 7), which substantially overlaps the presently claimed heat treatment time and temperatures. Said solution heat treatment temperature taught by Schetky overlaps heating above the beta transus.

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Concerning claims 3-7, 48, 49, because Schetky teaches a substantially overlapping alloy composition, processed in a substantially similar method, then substantially the same properties, such as elastic recovery are inherently present. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. The prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433. See also Titanium Metals Corp. v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985), see MPEP 2112.01.

Concerning claims 8, 24, 47, Schetky teaches said alloy has a beta phase (abstract), has linear elastic properties (column 4 line 16), and has pseudoelastic properties (column 3 line 14) and superelastic properties (column 3 lines 27-28), and has a matensitic structure (abstract).

Concerning claims 9-15, 50, 51, which mention said Ti-Mo-Al alloy is in the form of a medical device, Schetky teaches said alloy has excellent biocompatibility and is useful for a

variety of medical uses, including: orthodontic arch wires, a stent, catheter, dental implants, bone staples, eyeglass frames (column 3 lines 22-27).

Concerning claims 11-12, 22, which mention said Ti-Mo-Al alloy is welded, Schetky teaches said alloy exhibits superior weldability (column 2 line 59, column 5 line 15), when said alloy is formed and welded (column 5 line 15).

Concerning claim 46, Schetky teaches said alloy is formed into a wire, for example, 0.4 mm in diameter (column 9 lines 15-16).

Because the prior art teaches examples within the presently claimed alloying ranges, as well as a substantially identical product by process, it is held that Schetky anticipates the presently claimed invention.

# Claim Rejections - 35 USC § 103

- 4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 5. Claims 1-15, 22-24, 26-28, 32-35, 37-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schetky et al (US 6,258,182).

Schetky teaches a beta phase titanium alloy preferably comprising: 10-12% Mo, 2.8-4% Al, 0-2% Cr, and 0-4% Nb (see abstract), which overlaps or touches the boundary of the composition in instant claim 1. Schetky teaches examples within the instant composition range (see Table III, alloys 27, 28, and 36). While the preferred range taught by Schetky does not

overlap the alloys of independent claims 26 and 37, the alloys of claims 26 and 37 fall within the scope of the limits of Mo, Al, Cr, V, and Nb listed in the examples of Schetky in Table III columns 7 and 8, wherein said examples encompass: 8.4-12% Mo, 2.3-3.7% Al, 0-1.8% Cr, 0-1.8% V, 0-3.8% Nb. Overlapping ranges have been held to be a prima facie case of obviousness, see MPEP § 2144.05. It would have been obvious to one of ordinary skill in the art to select any portion of the range, including the claimed range, from the broader range disclosed in the prior art, because the prior art finds that said composition in the entire disclosed range has a suitable utility. See also Titanium Metals Corp. v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985).

Concerning the process limitations of dependent claims 2, 39-45, Schetky teaches cold working a wire up to 20% reduction, further heat treatment including solution heat treating 780-880°C (column 12 line 60), and aging at 200-400°C (column 11 lines 18) for 0.1-10,000 min (see Fig. 7), which overlaps the presently claimed heat treatment time and temperatures. Said solution heat treatment temperature taught by Schetky overlaps heating above the beta transus. Though Schetky does not teach a product produced by solution heating below the beta transus, the temperature range of solution heating given by Schetky overlaps the solution heat treatment range given in the instant specification typical of below the transus temperature (see [0056]). Concerning claim 42, Schetky does not specify said alloy product is further cooled in air. However, because the limitation of "cooled in air" is held to be met by the alloy of Schetky exposed to air and decreasing in temperature (wherein said decrease includes very minimal changes, such as 0.1°C), it is held to be within the scope of Schetky to further cool in air, substantially as presently claimed.

Concerning claims 3-7, 48, 49, because Schetky teaches a substantially overlapping alloy composition, processed in a substantially similar method, then substantially the same properties, such as elastic recovery are expected to be present. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. The prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433. See also Titanium Metals Corp. v. Banner, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985), see MPEP 2112.01.

Concerning claims 8, 24, 34, 35, 47, Schetky teaches said alloy has a beta phase (abstract), has linear elastic properties (column 4 line 16), and has pseudoelastic properties (column 3 line 14) and superelastic properties (column 3 lines 27-28), and has a materistic structure (abstract).

Concerning claims 9-15, 27, 28, 38, 50, 51, and 52, which mention said Ti-Mo-Al alloy is in the form of a medical device, Schetky teaches said alloy has excellent biocompatibility and is useful for a variety of medical uses, including: orthodontic arch wires, a stent, catheter, dental implants, bone staples, eyeglass frames (column 3 lines 22-27). Though Schetky does not specify

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forming said alloy into a file or drill for dental applications, because of the excellent biocompatability of the Ti-Mo-Al alloy taught by Schetky, it is held to be useful for a variety of medical and dental purposes, such as a file or drill.

Concerning claims 11-12, 17, 20, 22-23, 31-33, which mention said Ti-Mo-Al alloy is welded, Schetky teaches said alloy exhibits superior weldability (column 2 line 59, column 5 line 15).

Concerning claim 46, Schetky teaches said alloy is formed into a wire, for example, 0.4 mm in diameter (column 9 lines 15-16).

6. Claims 16-21, 29-31, and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schetky as applied to claims above, and further in view of Aizawa et al (US 5,658,207).

Schetky does not mention said Ti-Mo-Al alloy is formed into a portion of a golf club. However, Aizawa teaches that titanium alloys can be formed into golf club heads (column 1 line 10), and wherein said golf club head can be secured by welding or press fitting (column 6 lines 54-55). It would have been obvious to one of ordinary skill in the art to form the Ti alloy taught by Schetky into a golf club head taught by Aizawa, because Schetky teaches said alloy has excellent tensile strength properties (column 9 line 20).

7. Claims 25 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schetky as applied to claims above, and further in view of Davidson (US 6,238,491).

Schetky does not teach the application of a polymer coating to the instant Ti-Mo-Al alloy. However, Davidson teaches that similar Ti alloys used for medical implants can be coated in order to further improve biocompatability, wherein said coating can be a polymer (column 13 lines 40-46). It would have been obvious to one of ordinary skill in the art to coat the Ti-Mo-Al

alloy medical device taught by Schetky with a polymer coating as taught by Davidson, because Davidson teaches said coating improves biocompatability (column 14 lines 40-46).

## **Double Patenting**

8. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer <u>cannot</u> overcome a double patenting rejection based upon 35 U.S.C. 101.

9. Claims 26-38 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 28-40 of copending Application No. 10/755,085. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Claims 26-38 of the instant application appear to be identical to claims 28-40 of copending Application No. 10/755,085.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1-52 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims1-39 of copending Application No. 10/609003. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of US'003 are also drawn to a composition with 8-10% Mo, 2.8-6% Al, up to 2% V, up to 4% Nb, balance Ti; wherein said alloy exhibits an elastic recovery substantially as presently claimed (see US'003 at claims 3-10), is produced by solution heating, cold working, cooling in air, aging 350-550°C (US'003 at cl. 2, 11, 12).

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Claims 1-52 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-49 of copending Application No. 10/755034. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of US'034 are drawn to an overlapping alloy composition with 8-10% Mo, 2.8-6% Al, up to 2% V, up to 4% Nb, balance Ti (US'034 at cl. 4), wherein said alloy exhibits an elastic recovery substantially as presently claimed (see US'034 at claims 10-23), is produced an identical process of solution heating, cold working, cooling in air, aging 350-550°C (US'003 at cl. 6, 17, 31).

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

13. Claims 1-52 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 15-24 of copending

Application No. 10/869359. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of US'359 are drawn to an overlapping alloy composition with 8-10% Mo, 2.8-6% Al, up to 2% V, up to 4% Nb, balance Ti (US'359 at cl. 17), wherein said alloy is held to inherently exhibit an elastic recovery substantially as presently claimed, and said alloy product is produced a process of heat treating and cold working (US'359 at cl. 15, 18).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

14. Claims 1-52 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 10/755085. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of US'085 are drawn to an overlapping alloy composition with 8-10% Mo, 2.8-6% Al, up to 2% V, up to 4% Nb, balance Ti (US'085 at cl. 3), wherein said alloy exhibits an elastic recovery substantially as presently claimed (see US'085 at claims 5-10), is produced an identical process of solution heating, cold working, cooling in air, aging 350-550°C (US'085 at cl. 4, 45).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

#### Conclusion

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janelle Combs-Morillo whose telephone number is (571) 272-1240. The examiner can normally be reached on 8:30 am- 6:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Roy King can be reached on (571) 272-1244. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GEORGE WYSZOMIERSKI PRIMARY EXAMINER GROUP 1700

JCM June 9, 2005